JUL 2 0 2001

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K011253

II. 510(k) SUMMARY

Submitted By: Thai Nippon Rubber Industry, Ltd.
49-49/1, EPZ-1
Laemchabang Industrial Estate
Thungsukhla, Sriracha, Chonburi
Thailand
Telephone: 66-38-490258-9
Fax: 66-38-490414

Contact Person: Eli J. Carter
Consultant to Thai Nippon
1219 Little Creek Road
Durham, NC 27713

Date Prepared: April 19, 2001

Proprietary Name: One Touch or Private Label – Strawberry, Banana, or Vanilla

Common Name: Male Latex Condom

Classification Name: Latex Condom (21 CFR 884.5300)

Predicate Device: Lifestyle Contempo Strawberry, Vanilla or Banana Flavored Male Latex Condom 510(k)# K000408

Description of Device: This condom is made of a natural latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is straight-walled with a reservoir tip, and is designed to conform to established national and international voluntary standards including ASTM D3492, ISO 4074 and EN 600. The condom is offered in pink with strawberry flavoring, yellow with banana flavoring, and natural color with vanilla flavoring.

Intended Use of the Device:

This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV. If properly used, this condom will help reduce the risk of pregnancy without the serious side effects sometimes associated with other contraceptive methods.

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Technological Characteristics:

This condom has the same technological characteristics as the predicate condom identified above. Both are manufactured with the same approved flavor additives in the silicone lubricant. The flavor additives are used in the minimum quantity required to produce the intended effect as lubricant flavors, and all ingredients are listed as safe food flavor ingredients or enjoy FDA GRAS status for flavors. The condom design conforms to domestic and international regulations: ASTM D3492, ISO 4074, and EN 600. All physical testing, air inflation testing, colorfastness testing, including other in-process and final release testing revealed results in conformance with required specifications.

When compared to the predicate device, the condom intended to be introduced does not incorporate any significant changes in intended use, method of operations, materials, or design that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2001

Thai Nippon Rubber Industry, Ltd.
c/o Mr. Eli Carter
Consultant
1219 Little Creek Road
DURHAM NC 27713

Re: K011253
Flavored Male Latex Condom
Dated: April 19, 2001
Received: April 24, 2001
Regulatory Class: II
21 CFR §884.5300/Procode: 85 HIS

Dear Mr. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

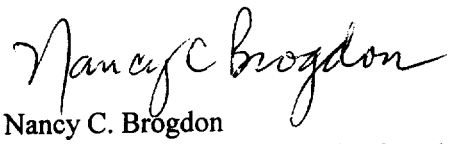
Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR §801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597,or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

VII. INDICATIONS FOR USE STATEMENT

510(k) Number	Not Known K011253
Device Name	Male Natural Rubber Latex Condom with Flavored Silicone lubricant (Strawberry, Vanilla, or Banana)
Indications for Use:	The Thai Nippon condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011253